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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,227	03/27/1998	MARTIN P. REDMON	4821-304	5249

7590 08/13/2002
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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/13/2002 24

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/049,227

Applicant(s)

REDMON ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 03 January 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-37.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


DWAYNE C. JONES
PRIMARY EXAMINER

Continuation of 3. Applicant's reply has overcome the following rejection(s): the previous claims rejection under 35 USC 112, paragraph 2 set forth at paragraph 9 of the office action mailed Nov. 2, 2000.

Continuation of 5. does NOT place the application in condition for allowance because: of reasons given previously in the office actions mailed Nov. 2, 2000 and July 5, 2001.

With respect to Applicant's arguments concerning the 102(e) rejection of claims 21, 29, Applicant is respectfully reminded that "consisting essentially of" language, limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). Please see MPEP 2111.03

With respect to the claims drawn to anhydrous forms of optically pure Fluoxetine, it is noted that the specification at page 15, lines 27-33 defines "anhydrous" as substantially free of unbound water or the amount of unbound water (if present) is insufficient to accelerate incompatibility between fluoxetine and lactose. Applicant argues that El-Rashidy disclose a fluoxetine composition containing an ingredient, dicalcium phosphate dihydrate, which contains water. Therefore, the disclosed compositions cannot be anhydrous. However, the Examiner respectfully submits that the term "anhydrous" as defined does not exclude all water (substantially free of water) and further that the water molecules appear to be bound to the dicalcium phosphate and therefore would not be expected to detrimentally affect the overall composition since, as the specification states, it is the presence of unbound water which is undesirable. The Examiner respectfully maintains that El-Rashidy discloses a dry fabrication process and that one of ordinary skill in the art would reasonably expect the ultimate fluoxetine compositions to be essentially free of water.